## DETAILED ACTION

### *Status of the Claims*

1. Claims 1-23 are pending.

Applicants' amendment filed October 28, 2009 is acknowledged. Applicants' response has been fully considered. Claims 1, 11, 15 and 21 have been amended, and new claims 22-23 have been added. Therefore, claims 1-23 are examined.

### *Maintained Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-23 are directed to an anabolic composition comprising cartilage, chondroitin sulfate, hyaluronic acid or collagen as an anti-neo-inflammatory agent; about 1 to 3 grams of at least one polar surface lipid; a plurality of L-amino acids and glycine; taurine or L-carnitine or both taurine and L-carnitine; a component of Polyoxyethylene Sorbitan Monooleate (TWEEN 80), Sorbitan monooleate (SPAN 80), grape seed extract, grape extract, and combinations thereof; and vitamins, minerals or trace elements.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification indicates that an anabolic composition can comprise three, four or five of the following components: Component #1 of 10-25 grams of molar ratio amino acids of Neocate; Component #2 of polar surface active lipid, high HLB surfactant such as Tween 80 may be used along with Components #1 and #2; Component #3 of extracellular matrix such as a proteoglycan aggregate complex of chondroitin sulfate covalently bonded to core protein; Component #4 of vitamins, Minerals and trace elements; Component #5 comprising phytozyme, amylase or other components; Component #5 (the second #5) with addition pro-biotic component (pages 17-24), the specification does not disclose a genus of variants for a plurality of

L-amino acids and glycine (part c) in the anabolic composition. A single species of amino acid mixtures of Neocate (page 17, line 20-21; Example 3) does not provide sufficient description for the whole genus of amino acids mixtures having a plurality of L-amino acids and glycine in an anabolic composition, when there is substantial variation within the whole genus of amino acid mixtures (part c). For example, the specification does not describe various amino acid mixtures (e.g., what amino acids and what amounts of these amino acids) used in an anabolic composition except for Neocate which is formulated as characteristic of human breast milk protein. Furthermore, what effects these amino acid mixtures would produce. Since there is no structure-function correlation for the amino acid mixtures in the anabolic composition, it is unpredictable regarding what amino acids and what amounts of amino acids would be included in the anabolic composition. The lack of description on the structure-function correlation for the amino acid mixtures in the anabolic composition, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

*Response to Arguments*

Applicants indicate claims 22-23 have been added to indicate that the composition comprises "a plurality of enantiomerically pure L-amino acids and glycine in molar ratios equivalent to that specified in the genetic code of a normal human tissue" (See page 6, lines 18-21; page 21, lines 9-11; page 24, lines 30-31 of the specification). There are sufficient recitations throughout the specification of human tissues that can be treated with the compositions of the subject invention, which mimic the tissues to be treated. Further, it would be

a matter of routine experimentation for a person skilled in the art to determine the molar ratios of a human tissue in need of treatment with the therapeutic compositions of the subject invention. For example, two references (Wilkerson, *J. Biological Chemistry,* 107, p. 377, 1934; and Rothberg *et al.,* J. *Investigative Dermatology,* Vol. 44, pp. 320-325, 1965) teach specific information about the amino acid compositions of epidermis and various components thereof. There is no requirement that a specification teach that which is well known in the art. It is well-settled law that a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption, and the Office Action fails to establish why a person of skill in the art would not have recognized the disclosure as a description of the invention defined by the claims. In this application, however, the structures of the amino acids recited in the claims is known; thus, the arguments regarding the written description issue are not germane to the invention claimed in this application. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested (pages 6-9 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because of the following reasons. While claims 22-23 have been added to indicate that the composition comprises "a plurality of enantiomerically pure L-amino acids and glycine in molar ratios equivalent to that specified in the genetic code of a normal human tissue", and it may be a matter of routine experimentation for a person skilled in the art to determine the molar ratios of a human tissue, however, the specification does not describe the use and effect of various human tissues' amino acid mixtures in the treatment of various damaged tissues except for Neocate, which is formulated as characteristic of human breast milk protein and used in the

treatment of Crohn's disease. While the structures of amino acids are known, the molar ratio of amino acids in the mixtures are not indicated, thus, the genus of "a plurality of enantiomerically pure L-amino acids and glycine" can encompass numerous embodiments (i.e., species) in the anabolic composition. Furthermore, there is no function indicated for various amino acid mixtures in the anabolic composition, it is unpredictable what amino acids and what amounts of amino acids would be included in the anabolic composition for the treatment of damaged tissue. In view of the foregoing, the rejection is maintained.

***Conclusion***

4. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached at 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
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